

MAR 10 2005

510(k) Summary

General Information

K043541

Classification	Class I
Trade Name	Endolink™ True Movement System™
Submitter	Novare Surgical Systems, Inc. 10440 Bubb Road Suite A Cupertino, CA 95014 Tel: 408-873-3161
Contact	Kerry Pope President & CEO

Intended Use

The Endolink™ True Movement System™ is intended for grasping, mobilization, dissection and transaction of tissue under direct and endoscopic visualization.

Predicate Devices

K984240	Endopath Endoscopic Instruments Ethicon Endo-Surgical, Inc.
K972510	Pivotal Grasper / Dissector / Scissors Imagyn Surgical

Device Description

The Endolink™ True Movement System™ (Endolink Instruments) are single use, sterile instruments that consist of a handle, jaws, and a shaft which includes distal and proximal articulating sections. The Endolink

Instruments are similar in size to other instruments and are designed for use through an incision or appropriately sized surgical trocars/ports. The instrument jaws (or scissor blades) are activated by compressing and releasing the handle. The handle can include a ratchet and ratchet release which allow the instrument jaws to be locked in place.

Materials

All materials used in the manufacture of the Endolink Instruments are suitable for this use and have been used in numerous previously cleared products.

Testing

Product testing was conducted to evaluate conformance to product specification. Testing included grasping, manipulating, cutting and suturing of tissue.

Testing comparing the Endolink Instruments to a commercially available predicate product was conducted. The products were used per their respective Instructions for Use. The results showed the Endolink Instruments were equivalent to the predicate device.

Summary of Substantial Equivalence

The Endolink Instruments are equivalent to the predicate products. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 10 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Novare Surgical Systems, Inc.
c/o Mr. Gregory Mathison
Regulatory Strategies, Inc.
3924 Cascade Beach Road
Lutsen, Minnesota 55612

Re: K043541

Trade/Device Name: Endolink™ True Movement System™
Regulation Number: 21 CFR 876.1500
Regulation Name: Laparoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: December 20, 2004
Received: December 22, 2004

Dear Mr. Mathison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,




for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): This application K 043541
Device Name: Endolink™ True Movement System™

Indications for Use: The Endolink™ True Movement System™ is intended for grasping, mobilization, dissection and transection of tissue under direct and endoscopic visualization.


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K043541

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)